STATE OF HAWAII REQUEST FOR SOLE SOURCE

STATE PROCUREMENT OFFICE STATE OF HAWAI!

Cost: \$95,780

TO:

Chief Procurement Officer

FROM:

Name of Vendor:

Department of Health / State Laboratories Division / Administration / Bioterrorism Response Laboratory

(Department / Division / Agency)

Pursuant to § 103D-306, HRS, and Subchapter 9, Chapter 3-122, HAR, the Department requests sole source approval to purchase the following:

Description of goods, services, or construction:

The MagNA Pure LC instrument is a fully automated walk-away system for the isolation and purification of DNA, RNA, mRNA and viral nucleic acids. The MagNA Pure system consists of the a bench-top instrument with a peltier heating component, cooling block sample carousel for automatic filling of samples, a cooling block for reaction tubes and 96-well plates, a cooling block for centrifuge adapters, a reagent reservoir rack, a barcode reader, an ultra-violet (UV) decontamination capability, heating blocks for temperature stability, a software package that supports reagent handling, sample tracking and record keeping. A computer station, operator training, and a service agreement that provides service on parts and labor for two year, including engineering updates, enhancements and preventive maintenance schedules.

Address: P.O. Box 50414 9115 Hague Road Indianapolis, IN 46250					
Term of Contract:	From:	То:	Prior Sole Source Reference No.:		

The goods, services, or construction has the following unique features, characteristics, or capabilities:

Roche Diagnostics Corporation

Roche Applied Science

The MagNA Pure system is a fully automated nucleic acid isolation and purification system that uses a proven magnetic bead isolation technology in tips. The MagNA Pure system does not employ vacuum or tubing on stage and there is no sample or reagent contact with the instrument during normal operations which minimize the risk of contamination, the peltier cooled sample storage allows for overnight operation of the instrument. The instrument allows for flexibility in sample dispensing range between 5-1000 µl; sample volume between 20-300 µl; and elution volume range of 25-100 µl. It also features a drop catcher that prevents drop loss during operation, an essential safeguard against contamination. The system uses RNAse free disposables and reagents which minimize cross contamination, a critical issue in molecular diagnostic assays. More importantly, the MagNA Pure instrument is a closed system, designed with a UV decontamination capability thus ensuring safety of the microbiologist during operation. Other unique features include software-supported reagent handling, sample tracking, record keeping, and generation of sample information, which enhances efficiency and greater productivity in the laboratory.

S. S. Number: <u>04-3-R</u>

REQUEST FOR SOLE SOURCE (Cont.)

How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work:

- Since the instrument is fully automated, it does not require user intervention enhancing productivity and efficiency in the laboratory.
- The MagNA Pure system utilizes a proven magnetic bead technology for the purification of high quality DNA or RNA or mRNA from various sources such as blood, blood cells, cell cultures, serum, tissues, stool, and environmental samples. This is very important in providing rapid molecular testing for bioterrorism agent detection, and for the detection of pathogens involved in infectious disease outbreak such as Norovirus, West Nile, and Severe Acute Respiratory Syndrome (SARS) virus.
- Since the instrument is a high-speed system, 32 samples can be loaded and processed in an hour allowing for faster turn-around time (TAT) for PCR detection of the target nucleic acid. Rapid TAT is critical in public health response to a BT event or during an outbreak investigation; early detection means early intervention and treatment.
- Some of the unique features described maximizes sample integrity and reduce the risk of cross and carry-over contamination which is a problem when dealing with sensitive tests.
- The UV decontamination capability is an important biosafety feature when dealing with BT and other highly

infectious agents.								
This instrument is being purchased with federal Bioterrorism (BT) funds.								
The following other possible sources for the goods, services, or construction were investigated because:								
Qiagen Mdx-\$170,000; did not have the UV decontamination capability that MagNA Pure symbiosafety feature. The MagNA Pure system is currently being used at the BT Rapid Response and Advance Tech (BRRAT) of the CDC in Atlanta. Thus, protocols for rapid molecular assays of potential bioagethis laboratory (BRRAT) using this MagNA Pure platform.	nnology Laboratory							
Bioterrorism Preparedness Microbiologist & Lab Coordinator	Fax: (808) 453-5995							
I certify that the information provided above is to the best of my knowledge, true, correct and that the goods, services, or construction are available through only one source.								
Department / Agency Head Date								
Deputy Director of Health								
Title (If other than Department Agency Head)								
Chief Procurement Officer's Comments:								
Please ensure adherence to applicable administrative and statutory requirements.								
Expenditure may be processed through a purchase order: YesNo If no, a contra funds certified.								
Approved Denied Chief Procurement Off	Dete S.S. Number: <u>04-3-</u>							

STATE OF HAWAII NOTICE OF SOLE SOURCE

The Chief Procurement Officer is in the process of reviewing the request from the <u>Department of Health</u>, <u>State Laboratories</u> <u>Division</u>, <u>Bioterrorism Response Laboratory</u> for the sole source purchase of the following goods, services, or construction:

The MagNA Pure LC instrument is a fully automated walk-away system for the isolation and purification of DNA, RNA, mRNA and viral nucleic acids. The MagNA Pure system consists of the a bench-top instrument with a peltier heating component, cooling block sample carousel for automatic filling of samples, a cooling block for reaction tubes and 96-well plates, a cooling block for centrifuge adapters, a reagent reservoir rack, a barcode reader, an ultra-violet (UV) decontamination capability, heating blocks for temperature stability, a software package that supports reagent handling, sample tracking and record keeping. A computer station, operator training, and a service agreement that provides service on parts and labor for two year, including engineering updates, enhancements and preventive maintenance schedules.

Vendor:

Roche Diagnostics Corporation

Roche Applied Science

Address:

P.O. Box 50414 9115 Hague Road Indianapolis, IN 46250

Term of Contract:	From: To:	Cost: \$95,780	
Direct any inquiries to	:	i i	
Department:	Health, State Laboratories Division	Phone Number: (808) 453-5993	
•	Bioterrorism Response Laboratory		
Contact Name/Title:	Rebecca H. Sciulli	į	
	Bioterrorism Microbiologist & Coordinator	Fax Number: (808) 453-5995	
Address:	2725 Waimano Home Road	· · ·	
	Pearl City, Hawaii 96782		

Date Notice Posted:

A copy of this notice of sole source shall be posted by the Chief Procurement Officer and the purchasing agency in an area accessible to the public, at least seven (7) calendar days prior to any approval action.

Submit written objections to this notice to issue a sole source contract within seven (7) calendar days from the date this notice was posted to:

Chief Procureme	nt Officer		
Office/Agency			
Address			